

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	
LITIGATION)	MDL No. 1456
_____)	Master Case No. 01-12257-PBS
)	
THIS DOCUMENT RELATES TO:)	Subcategory Case No. 06-11337-PBS
)	
<i>United States of America ex rel. Ven-a-Care</i>)	
<i>of the Florida Keys, Inc. v. Dey, Inc., et al.,</i>)	
Civil Action No. 05-11084-PBS, and)	
)	
)	

**MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION
TO BIFURCATE MEDICARE AND MEDICAID CLAIMS¹**

Trying the Medicare case separately from the Medicaid part of the case will mean a shorter, clearer, more efficient trial on claims that encompass 80% of the damages – thereby providing a cogent incentive to settle the remaining claims, whichever way the first trial ends. As the Court and parties have acknowledged, the presentation of evidence concerning the states' Medicaid programs is likely to be cumbersome, particularly as the Dey defendants have signaled their intention to present extensive testimony and other evidence from a large number of states. Because the Medicare case can be presented more effectively by both sides if tried separately, and might obviate the need for further proceedings, plaintiffs ask the Court to bifurcate the Medicare claims from the Medicaid claims, and try the Medicare claims first.

BACKGROUND

Beginning at a Motion hearing on June 18, 2008, the Court raised the issue of the complexity of presenting evidence for the fifty states' Medicaid programs. *See, e.g.,* Transcripts

¹ Plaintiffs have filed this Motion and Memorandum only in the Dey case. Should the Roxane case not be resolved, plaintiffs would file the identical Motion in that case as well.

of June 18, 2008, Motion Hearing, *passim* (summary judgment presentations); November 13, 2008, Status Conference at 5-12, 43 (same); January 19, 2010, Motion Hearing at 15 (trial evidence). Last November, plaintiffs suggested first trying only the Medicare claims against both Dey and Roxane, pointing out that those claims encompass 80% of the total damages and would permit a more streamlined trial. *See* United States' Reply Memorandum In Further Support of United States' Motion to Consolidate Cases for Trial, Docket No. 6660, (Sub. 537) ("U.S. Reply Brief") at 9; Transcript of January 19, 2010, Motion Hearing at 10-12.² At the January 19 hearing, the Court posited structuring an initial trial dealing only with "two defendants, ipratropium bromide, [and] Medicare." *Id.* at 13-14. The United States later clarified its support for that approach, although arguing for inclusion of albuterol, the only other Medicare drug. Transcript of January 26, 2010, motion hearing at 46-47. More recently, at the Status Conference on March 26, 2010, counsel for the United States reiterated that, even if trial were to go forward only against the Dey defendants, it still made sense to bifurcate the Medicare and Medicaid claims for trial. Transcript of March 26, 2010, Status Conference ("3/26 Tr."), at 11, 16.

ARGUMENT

The Medicare claims implicate a single federal agency, one reimbursement formula, fewer drugs (only two), and a shorter time period. This part of the case, although still complex, is less so than the Medicaid part of the case and, for reasons of economy and expedition, should

² Plaintiffs initially suggested "sequencing" the trial, with Medicare claims tried first, then the Medicaid claims, to the same jury. U.S. Reply Brief at 9. The United States later indicated its agreement with the Court's suggestion of a separate trial with both defendants on the Medicare claims only. *See* Transcript of January 26, 2010, motion hearing at 46-47.

be tried first, and separately. The array of proposed evidence involved in trial of the Medicaid claims is both more complicated and more voluminous, and will require additional discovery, more challenges to (and consequently more rulings on) admissibility, and significant additional expense for bringing state Medicaid witnesses to Massachusetts to testify.³ Moreover, in some very significant respects the evidentiary records are different, and presenting them simultaneously would cause unnecessary confusion. Finally, a jury verdict on the Medicare claims would likely help settle the Medicaid part of the case. The Court should exercise its broad discretion to bifurcate the Medicare claims for trial.

A. The Court May Bifurcate Any Issue to Promote Efficiency and Reduce Expense

A decision whether to bifurcate claims or issues is within the discretion of the district court. *Barr Labs., Inc. v. Abbott Labs.*, 978 F.2d 98, 115 (1st Cir. 1992). In deciding whether to order separate trials under Rule 42(b) of the Federal Rules of Civil Procedure, the court weighs a variety of issues, including convenience for the parties and court, and whether separate trials will minimize expense and delay. *See, e.g., Chapman v. Bernard's Inc.*, 167 F. Supp. 2d 406, 417 (D. Mass. 2001) (allowing bifurcation even when some witnesses would have to testify at both trials, where trial of first issue would be outcome determinative); 9A CHARLES ALAN WRIGHT & ARTHUR R. MILLER, *FEDERAL PRACTICE AND PROCEDURE* § 2389, (3d ed. 2008) (Rule 42(b) is “sweeping in its terms and allows the district court . . . to grant a separate trial of any kind of issue in any kind of case.”). Here, for a host of reasons, separate trials are warranted, will

³ In light of the Court’s disinclination to strike designated deposition testimony where the United States was not present to cross-examine, and its indication that there must be testimony from every state, 3/26 Tr. at 20, plaintiffs now expect to call more state witnesses to testify live (whether in its case-in-chief or in rebuttal) than previously anticipated.

promote the ends of justice, and will impose a more manageable demand on the jury.

B. A Medicare-only Trial Would be Leaner

Instead of the 47 state programs implicated in the Medicaid claims, the Medicare case involves a single federal agency, four Durable Medical Equipment Regional Carriers (“DMERCs”), one basic reimbursement scheme, and a shorter damages period with a certain cut-off date (December 31, 2003), while accounting for over 80 percent of the total damages alleged by the government. The provider claims at issue in Medicare are distinct from those at issue under Medicaid, and are governed by a different reimbursement methodology. In addition, as would be expected and as was abundantly clear in the parties’ first pre-trial designations, there is simply more evidence required to try both claims at once.

C. Trying Both Claims Together Imposes a Greater Burden on the Jury and Could Lead to Juror Confusion

Having separate trials of the Medicare and Medicaid pieces of the case is the most practical way to present the claims to a jury. It would be an enormous demand on a single jury to hear both, not only because of the time required to present and defend both aspects of the case, but also in the sheer volume of very complicated evidence, much presented by experts and through deposition testimony. Jurors would be called upon to learn two separate government programs with different reimbursement mechanisms. As compared to a Medicare-only trial, trying both Medicare and Medicaid claims at the same time would be more unwieldy and, as Dey’s counsel acknowledged at the most recent status conference, would require a longer trial. *See* 3/26 Tr. at 10 (because “it involves both 47 Medicaid programs [and] the entire Medicare program . . . I don’t see how this trial is less than six to eight weeks.”)

Litigating the Medicaid claims with the Medicare claims would significantly increase

both the complexity and volume of evidence. The government's expert has calculated damages with respect to 48 states, and although the states' reimbursement algorithms have important core features in common, which are of greater import than minor variations in formulae, defendants have made clear their intent to emphasize the differences among state reimbursement methodologies and to introduce distinct state knowledge of pricing terms and practices. Dey designated at least 1400 documents concerning individual state Medicaid programs as trial exhibits (*see* 3/26 Tr. at 13: "We have designated an average of 31 documents per state.").⁴ Even more to the point is the extensive volume of testimony to be offered: Dey has initially designated over 80 state witnesses to present at trial through deposition testimony.

Simply considering and ruling on the expected objections to evidence and deposition testimony, not to mention addressing a number of other pre-trial issues attendant only to the Medicaid part of the case, will demand a significant expenditure of resources by the Court in advance of, and during, trial.⁵ Even if Dey reduces its designations, as urged by this Court at the status conference, to prepare and present the Medicaid case involves complications requiring a significant expenditure of resources not presented by a Medicare-only trial, an effort that could prove unnecessary. *See* Section E, *infra*.

Moreover, and not surprisingly, trial of the Medicare and Medicaid claims will involve

⁴ In a Medicare trial, the plaintiffs would expect to introduce some evidence concerning defendants' other drugs (reimbursed by Medicaid) to show motive, intent, and plan, pursuant to Fed. R. Evid. 404(b), but nowhere near 1400 documents.

⁵ For example, determination of the issue raised about Professor Duggan's damages extrapolations to different states would not be necessary prior to a Medicare-only first trial, the issues concerning government knowledge would be vastly simplified if focused solely on the federal government and Medicare, and only through 2003, and many of the policy arguments raised by defendants' experts, which plaintiffs are moving to exclude, arise only in the Medicaid arena.

different evidentiary records. As an initial matter, the Court suggested that “[w]e need to hear from Medicaid officials in every state” about each state’s program. 3/26 Tr. at 20. While the United States questions the necessity for this, particularly in light of the underlying similarities of the reimbursement formulae and the detailed summaries of the Medicaid programs that have been prepared in this case, there is no doubt that the evidence will be different and more complex if both Medicare and Medicaid are tried together, because different laws and regulations govern each program. Specifically, by both statute and regulation, Medicare reimbursement for the drugs at issue was expressly based on AWP. This Court and the First Circuit have already ruled that, at minimum, the term AWP as used in the context of Medicare reimbursement is not a term of art in the industry, but is to be construed according to its plain meaning. Accordingly, the universe of “government knowledge” evidence admitted in a Medicare-only trial would be severely curtailed, especially since what individual state Medicaid officials thought about AWPs and WACs is simply not relevant to the federal Medicare program. In a trial of both parts of the case, were the Court to permit the introduction of government knowledge evidence relating to state Medicaid programs (for example, deposition testimony from some state Medicaid officials that they believed AWP was a “list” price),⁶ such evidence would not be admissible as to the Medicare claims, and consequently would invite juror confusion.

⁶ The United States believes there are solid grounds to exclude such evidence as to both programs, and intends to move to exclude the so-called “government knowledge evidence,” but recognizes that the programs operate pursuant to distinct regulatory schemes and so it is possible that the Court could make different rulings as to each.

D. The Medicaid Case Requires That Additional Depositions Be Taken and Additional Witnesses Be Brought to Boston

Also as discussed at the last status conference, the Medicaid case presents the additional complication that Dey has designated deposition testimony from state Medicaid witnesses where the United States was not present. A large number of the deposition transcripts designated by Dey were of depositions from state litigation where the United States was not a party and so was not cross-noticed (indeed, some of the depositions occurred before the United States even intervened in the three *qui tam* cases), and therefore had no opportunity to cross-examine. As discussed at the most recent status conference, 3/26 Tr. at 17-22, if such testimony is to be admitted under Fed. R. Civ. P. 32(a), plaintiffs will need to fly to those various states and conduct cross-examination for trial, or subpoena the witnesses to testify live. As a practical matter, plaintiffs will likely do a combination – that is, schedule depositions in order to cross-examine some of the witnesses, and bring others to Boston to testify. Whether the parties' attorneys fly to distant states in advance of trial for depositions, or the witnesses are brought to Boston to testify live, substantial additional resources will be expended for travel – to obtain state testimony that may not even be needed.

E. Trial on the Medicaid Claims Could Prove Unnecessary

Once the jury has rendered a verdict on the Medicare claims that represent 80% of the damages, there would be increased motivation for, and a significant likelihood of, reaching a settlement, whichever way the jury finds. *See* 3/26 Tr. at 23-24 (parties agreed with Court that as a practical matter they would be likely to settle Medicaid claims following Medicare-only trial). Given the likelihood the parties could reach agreement on the Medicaid claims following a Medicare-only trial, it makes the most sense for the Court to rule now that the Medicare claims

will be tried separately – thus enabling the parties to focus on the Medicare case and avoid expending any additional resources on state depositions and preparation of the Medicaid case and defenses until after the Medicare trial – after which it might become moot. Under these circumstances, bifurcation would best serve the interests of justice.

Bifurcation is appropriate where, as here, trial of all the issues together would be “extensive and expensive” and the later trial might be mooted by the first. *See, e.g., In re: Paoli R.R. Yard PCB Litig.*, 113 F.3d 444, 452 n. 5 (3d Cir. 1997) (where trial of first issues of plaintiffs’ exposure to PCBs “lasted three weeks, involved dozens of witnesses and obviated the need for trial” on liability, which would have involved “more complicated issues,” the district court’s bifurcation “preserved judicial resources and reduced expenses of the parties”); *In re: Beverly Hills Fire Litig.*, 695 F.2d 207, 216-217 (6th Cir. 1982) (holding that trial court’s bifurcation was reasonable where trial of first issue alone took thirty-two days and issue could have been determinative or enhanced likelihood of settlement). Here, as in *Beverly Hills Fire*, bifurcation would promote judicial economy because a separate Medicare trial could eliminate the need for a subsequent trial on Medicaid, since a jury verdict on the Medicare claims, by presaging the outcome of the Medicaid case, would assist in resolving those claims without trial.

CONCLUSION

For the foregoing reasons, and because Dey will not be prejudiced by the bifurcation and in fact will save resources by having a Medicare-only trial, the Court should bifurcate the Medicare and Medicaid aspects of the case for purposes of trial, and order that trial on the Medicare claims will proceed first.

Respectfully submitted,

TONY WEST
ASSISTANT ATTORNEY GENERAL

CARMEN M. ORTIZ
UNITED STATES ATTORNEY

Joyce R. Branda
Daniel R. Anderson
Laurie A. Oberembt
Civil Division
Commercial Litigation Branch
P. O. Box 261
Ben Franklin Station
Washington, D.C. 20044
(202) 514-3345

FOR THE RELATOR,

James J. Breen
The Breen Law Firm, P.A.
5755 Northpoint Parkway, Suite 260
Alpharetta, GA 30022
Tel. (770) 740-000
fax: (954) 499-1173

By: /s/ Barbara Healy Smith
George B. Henderson, II
Barbara Healy Smith
James J. Fauci
Assistant U.S. Attorneys
United States Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3272

Gary Azorsky
Susan Schneider Thomas
Roslyn G. Pollack
Berger & Montague, P.C.
1622 Locust St.
Philadelphia, PA 19103
(215) 875-3090

CERTIFICATE OF SERVICE

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April 12, 2010

/s/ James J. Fauci
James J. Fauci
Assistant U.S. Attorney